

IN THE CLAIMS:

Amend the claims as follows:

1 1 (currently amended). A method for determining whether blood in a stool came
2 from an upper gastrointestinal site or a lower gastrointestinal site, comprising the steps of:

3 (a) collecting a stool sample and preparing it for analysis by spectroscopy;

4 (b) determining a sample absorption spectra of the stool sample; and

5 (c) determining whether the blood in the stool came from the upper
6 gastrointestinal site or for the lower gastrointestinal site based on an analysis of the sample
7 absorption spectra.

1 2 (currently amended). The method of claim 1 wherein step (c) ~~(e)~~ includes
2 performing the analysis to determine if absorption peaks of the sample absorption spectra are
3 present at approximately 540 nanometers and 576 nanometers, and determining that the blood in
4 the stool sample came from the lower ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~
5 present.

1 3(currently amended). The method of claim 1 wherein step (c) ~~(e)~~ includes
2 performing the analysis to determine if an absorption peak of a main Soret band of the sample
3 absorption spectra is closer to approximately 408 nanometers than to 415 nanometers, and
4 determining that the blood in the stool sample came from the upper gastrointestinal tract if the
5 main Soret band is closer to 408 nanometers.

1 4(currently amended). The method of claim 1 wherein step (c) ~~(e)~~ includes
2 performing the analysis to determine if absorption peaks of the sample absorption spectra are
3 present at approximately 540 nanometers and 576 nanometers and if an absorption peak of a
4 main Soret band of the sample absorption spectra is closer to approximately 408 nanometers than
5 to 415 nanometers, and determining that the blood in the stool sample came from the lower
6 ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~ present and if the main Soret band is
7 closer to 415 ~~408~~ nanometers.

1 5 (currently amended). A method for determining whether blood in a stool came
2 from an upper gastrointestinal site or a lower gastrointestinal site, comprising the steps of:

3 (a) placing the stool sample into a sample tube containing a liquid buffer to create a
4 sample stool suspension;

5 (b) separating the sample stool suspension into a particulate matter portion and a
6 liquid portion to create a fecal extract;

7 (c) filtering an amount of the fecal extract through a sample filter causing
8 hemoglobin and related molecules present in the fecal extract to adhere to the sample filter;

9 (d) determining a sample absorption spectra of the sample filter relative to an
10 absorption spectra of a reference filter that has not been exposed to the fecal extract using a
11 spectrophotometer; and

12 (e) determining whether the blood in the stool came from the upper gastrointestinal
13 site or for the lower gastrointestinal site based on a analysis of the sample absorption spectra.

1 6 (currently amended). The method of claim 5 wherein step (e) includes
2 performing the analysis to determine if absorption peaks of the sample absorption spectra are
3 present at approximately 540 nanometers and 576 nanometers, and determining that the blood in
4 the stool sample came from the lower ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~
5 present.

1 7 (original). The method of claim 5 wherein step (e) includes performing the analysis
2 to determine if an absorption peak of a main Soret band of the sample absorption spectra is closer
3 to approximately 408 nanometers than to 415 nanometers, and determining that the blood in the
4 stool sample came from the upper gastrointestinal tract if the main Soret band is closer to 408
5 nanometers.

1 8 (currently amended). The method of claim 5 wherein step (e) includes
2 performing the analysis to determine if absorption peaks of the sample absorption spectra are
3 present at approximately 540 nanometers and 576 nanometers and if an absorption peak of a
4 main Soret band of the sample absorption spectra is closer to approximately 415 ~~408~~ nanometers
5 than to ~~408~~ 415 nanometers, and determining that the blood in the stool sample came from the
6 lower ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~ present and if the main Soret
7 band is closer to 415 ~~408~~ nanometers.

1 9 (original). A method for determining whether blood in a stool sample came from an
2 upper gastrointestinal site or a lower gastrointestinal site comprising the steps of:

3 (a) placing the stool sample into a sample tube containing a liquid buffer to create a
4 sample stool suspension;

5 (b) separating the sample stool suspension into a particulate matter portion and a

6 liquid portion to create a fecal extract;

7 (c) filtering an amount of the fecal extract through a sample nitrocellulose filter
8 causing hemoglobin and related molecules present in the fecal extract to adhere to the sample
9 nitrocellulose filter;

10 (d) determining a sample absorption spectra of the sample nitrocellulose filter relative
11 to an identical reference nitrocellulose filter that has not been exposed to the fecal extract using a
12 spectrophotometer; and

13 (e) classifying the type of gastrointestinal bleed based on a mathematical analysis of
14 the sample absorption spectra.

1 10 (currently amended). The method of claim 9 wherein step (e) includes
2 performing the analysis to determine if absorption peaks of the sample absorption spectra are
3 present at approximately 540 nanometers and 576 nanometers, and determining that the blood in
4 the stool sample came from the lower ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~
5 present.

11 (original). The method of claim 9 wherein step (e) includes performing the analysis to determine if an absorption peak of a main Soret band of the sample absorption spectra is closer to approximately 408 nanometers than to 415 nanometers, and determining that the blood in the stool sample came from the upper gastrointestinal tract if the main Soret band is closer to 408 nanometers.

12 (currently amended). The method of claim 9 wherein step (e) includes performing the analysis to determine if absorption peaks of the sample absorption spectra are present at approximately 540 nanometers and 576 nanometers and if an absorption peak of a main Soret band of the sample absorption spectra is closer to approximately 415 ~~408~~ nanometers than to ~~408~~ 415 nanometers, and determining that the blood in the stool sample came from the lower ~~upper~~ gastrointestinal tract if the absorption peaks are ~~not~~ present and if the main Soret band is closer to 415 ~~408~~ nanometers.

13 (original). The method of claim 9 wherein the sample buffer belongs to a group of aqueous hypotonic buffers that includes TE buffer comprised of 0.01M Tris[Hydroxymethyl]aminomethane, 0.001 M Ethylenediaminetetraacetic acid adjusted to pH 7.4.

1 14 (original). The method of claim 9 wherein the stool particulate matter is separated
2 from the liquid phase by centrifugation and the resulting supernatant fraction becomes the fecal
3 extract.

1 15 (original). The method of claim 9 wherein the stool particulate matter is separated
2 from the liquid portion using a sample cassette, where the stool suspension is passed through a
3 removable particulate barrier allowing the fecal extract to pass through the sample nitrocellulose
4 filter and deposit the hemoglobin and related molecules onto the sample nitrocellulose filter.

1 16 (original). The method of claim 9 wherein the sample nitrocellulose filter and the
2 reference nitrocellulose are wetted with a 60% glycerol by volume sample buffer to increase the
3 translucency of the nitrocellulose sample filter aiding in the acquisition of the sample absorption
4 spectra.

1 17 (original). The method of claim 9 wherein the mathematical analysis of the sample
2 absorption spectra is accomplished by use of a trained artificial neural network running on a
3 computing device.

18 (original). The method of claim 9 wherein the mathematical analysis of the sample absorption spectra is a Simplex method implemented on a processor and using coefficients obtained from standard spectra for ferrohemoglobin, ferrihemoglobin, urobilinogen and fecal supernatant to maximize the function:

$$Z = \varepsilon_{1,\lambda 420}x_1 + \varepsilon_{2,\lambda 420}x_2 + \varepsilon_{3,\lambda 420}x_3 + \varepsilon_{4,\lambda 420}x_4$$

where ε is the absorption coefficient for the indicated component (1-4) at the indicated wavelength (λ) obtained from the standard spectra, and x is the number of units of the indicated component (where component 1 is ferrohemes, component 2 is ferrihemes, component 3 is fecal supernatant, and component 4 is urobilinogen) and subject to the following constraining equations:

$$A_{\lambda 412}/\varepsilon_{2,\lambda 412} = \varepsilon_{1,\lambda 412}x_1 + \varepsilon_{2,\lambda 12}x_2$$

$$0 \geq x_4 - x_3$$

$$A_{\lambda 412} = \varepsilon_{1,\lambda 412}x_1 + \varepsilon_{2,\lambda 412}x_2 + \varepsilon_{3,\lambda 412}x_3 + \varepsilon_{4,\lambda 412}x_4$$

$$A_{\lambda 440} = \varepsilon_{1,\lambda 440}x_1 + \varepsilon_{2,\lambda 440}x_2 + \varepsilon_{3,\lambda 440}x_3 + \varepsilon_{4,\lambda 440}x_4$$

$$A_{\lambda 494} = \varepsilon_{1,\lambda 494}x_1 + \varepsilon_{2,\lambda 494}x_2 + \varepsilon_{3,\lambda 494}x_3 + \varepsilon_{4,\lambda 494}x_4$$

$$A_{\lambda 475} = \varepsilon_{1,\lambda 475}x_1 + \varepsilon_{2,\lambda 475}x_2 + \varepsilon_{3,\lambda 475}x_3 + \varepsilon_{4,\lambda 475}x_4$$

$$A_{\lambda 559} = \varepsilon_{1,\lambda 559}x_1 + \varepsilon_{2,\lambda 559}x_2 + \varepsilon_{3,\lambda 559}x_3 + \varepsilon_{4,\lambda 559}x_4$$

$$A_{\lambda 578} = \varepsilon_{1,\lambda 578}x_1 + \varepsilon_{2,\lambda 578}x_2 + \varepsilon_{3,\lambda 578}x_3 + \varepsilon_{4,\lambda 578}x_4,$$

where A is the absorption value at the indicated wavelength (λ) of the sample absorption spectra.

1 19 (original). The method of claim 9 wherein the mathematical analysis of the sample
2 absorption spectra is according to a Gaussian Jordan elimination algorithm, a singular value
3 decomposition of them, or an artificial neural network algorithm.

1 20 (original). The method of claim 9 wherein the classification of the gastrointestinal
2 bleed is determined by visual inspection of the sample absorption spectra.

1 21 (original). The method of claim 9 wherein the method to purify the hemoglobin and
2 hemoglobin products in the stool sample is one of an affinity binding method, a phase separation
3 method, a hydrophobic interaction method, and an antibody selection method.

1 22 (original). The method of claim 9 wherein the sample absorption spectrum is
2 obtained over the range of 400 to 600 nanometers.

1 23 (currently amended). The method of claim 9 wherein the sample spectra are
2 obtained from ranges of light wavelengths including infra-red wavelengths or and a small
3 number of discrete wavelengths.

1 24 (original). The method of claim 23 wherein the amount of ferriheme and ferroheme
2 present in the fecal extract is determined by one of an infra-red spectroscopy method and a
3 Fourier transform infra-red spectroscopy (FTIR) method.

25(withdrawn).

26(withdrawn).

27(withdrawn).

28(withdrawn).

29(withdrawn).